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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,186	08/23/1999	HANS J. HANSEN	018733/0942	4908

7590 09/10/2002

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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909 7590 07/25/2002
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EXAMINER

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78

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*Reviewed
9/10/02*

Office Action Summary

Application No.

382,186

Applicant(s)

HANSEN et al

Examiner

SAUNDERS

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/3/01 & 3/28/02
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 31, 33-34, 37-48, 50 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 33-34 is/are allowed.
- ☒ Claim(s) 31, 37-48, 50 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawing correction, filed on 12/3/01 is ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Amendments of 12/3/01 and 3/28/01 (Papers 11 and 16) have been entered.

Claims 31, 33-34, 37-48 and 50 are pending and under examination.

Applicant's amendments and urgings have overcome 112, second paragraph rejection of record; new 112, second paragraph rejections follow:

Claims 31, 37-48 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is confusing as to how the claimed "set of expression cassettes" is able to produce a bispecific Fab'-ScFv fusion protein. The claim requires each cassette to encode an "ScFv linked to a Fd-fragment." These two expression cassettes would not produce any bispecific Fab'-ScFv fusion protein-- e.g. what encodes the L-chain of Fab'? The limitations of claim 50 must be incorporated into claim 31 in order to completely describe the claimed "set", and applicant must clearly indicate the differences between each member of the pair of cassettes.

Claims 37-38 are confusing because they recite humanized antibody or a fragment of a humanized antibody. Base claim 33 does not encompass production of a humanized antibody and the only humanized antibody fragment encompassed would be a Fab' fragment.

Claims 37-48 are confusing because they all, directly or indirectly, refer to the "construct of claim 33", which is directed to a "method of preparing" and not to a "construct". Where "construct" is recited in claim 33 is in the first line of each of parts (1)(A), (1) (B), (2) (A) and

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(2) (B). If claims 37-48 refer to one of these constructs it is not clear which one of these is intended.

Claims 31 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The "set of cassettes" claimed would not enable the production of a bispecific Fab'-ScFv fusion protein.

Specifically, since both members of the set recited in claim 31, encode an ScFv fused to an Fd, and no member encodes an L-chain to pair with the Fd, it would be impossible to produce any Fab' component of the bispecific antibody.

The previously stated 101 and 103 double patenting rejections have been overcome by applicant's cancellation of conflicting claims in the instant and copending applications.

Applicant's amendment has overcome prior art rejections of record.

Claims 31 and 50 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Bosslet et al. (U.S. 5,959,083 or EP 0,517,024).

Bosslet et al. show a set of nucleic acid expression vectors that encode an F(ab')₂-ScFv fusion protein of formula II. The construct encoding VLI-CK would correspond precisely to that recited in instant claim 50. The construct encoding Vh1-CH1 fused to the VH2-VL2 encodes more than what is instantly recited in claim 31. That is, it encodes more than the Fd, in order to

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provide for a hindge region. However, "comprising" language of claim 31 permits the recited cassette construct to encode more than the recited Fd.

Claims 33-34 and 37-48 are allowable over prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

July 24, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644